

PTO/SB/08A (04-02)
Approved for use through 04/30/2003, OMB 0651-003
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 4

Complete if Known

Application Number	10/046,454
Filing Date	October 19, 2001
First Named Inventor	DUDLEY, R.
Art Unit	1617
Examiner Name	JIANG, S.
Attorney Docket Number	01917581

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
SAD		US- 4,663,157	05-05-1987	Brock, E.D.	
		US- 4,699,779	10-13-1987	Palinczar, V.	
		US- 5,023,252	06-11-1991	Hsieh, D.	
		US- 5,446,025	08-29-1995	Lu, M.F.	
		US- 5,731,303	03-24-1998	Hsieh, D.	
		US- 5,891,462	04-06-1999	Carrara, D.	
		US- 6,503,894	01-07-2003	Dudley, R.E.	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number ⁴ Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
SAD		AU 4998490	09-20-1990	Amway Corp.		
		AU 9141391	06-25-1992	Theratech Inc.		
		EP 189861	08-06-1986	Showa Denko		
		EP 332147	09-13-1989	Warner-Lambert		
		EP 552405	11-25-1998	Lintec Corp.		
		EP 811381	05-02-2003	Permotech N.V.		

Examiner
Signature


Date
Considered

10/14/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.


 JUL 11 2003
 PORTLAND, OREGON POST OFFICE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known

(Use as many sheets as necessary)

Sheet	2	of	4
-------	---	----	---

Application Number	10/046,454
Filing Date	October 19, 2001
First Named Inventor	DUDLEY, R.
Art Unit	1617
Examiner Name	JIANG, S.
Attorney Docket Number	01917581

[illegible]

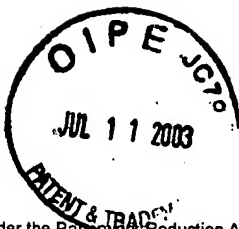
FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
		Country Code ³ Number ⁴ Kind Code ⁵ (if known)				
SP		GB 1158283	07-16-1969	Foster-Milburn		
		JP 62-011675	08-02-1994	TEZUKA		
		WO 87/03473	06-18-1987	Hsieh, D.		
		WO 92/07586	05-14-1992	Beecham Group PLC		

Date
Considered

*EXAMINER: Initial if reference considered whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, Washington, DC 20231.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08A (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 34

of 34

C mplete if Known

Application Number	10/046,454
Filing Date	October 19, 2001
First Named Inventor	DUDLEY, R.
Art Unit	1617
Examiner Name	JIANG, S.
Attorney Docket Number	01917581

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
SAD		US- 5,730,987	03-1998	Omar	
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			
		US-			

RECEIVED
JUL 18 2003
TECH CENTER 1600/2900

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ Number * Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T ⁶
SAD		WO 99/24041 A1	05-20-1999	Cellegy		
		WO 96/27372 A1	09-12-1996	Int'l Medical		
		WO 93/25168 A1	12-23-1993	Theratech Inc.		

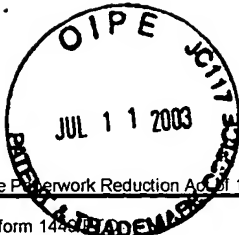
Examiner
SignatureDate
Considered

10/14/03

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

3

of

4

Application Number

10/046,454

Filing Date

October 19, 2001

First Named Inventor

DUDLEY, R.

Art Unit

1617

Examiner Name

JIANG, S.

Attorney Docket Number

01917581

RECEIVED
JUL 17 2003
TECH CENTER 1600-2900**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SAO		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1996, filed on March 28, 1997.	
		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-KSB) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1997, filed on March 31, 1998.	
		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1998, filed on March 22, 1999.	
		CELLEGY PHARMACEUTICALS, INC. Annual Report (Form 10-K) pursuant to The Securities Exchange Act of 1934 For the Fiscal Year Ended December 31, 1999, filed on March 14, 2000.	
		CELLEGY PHARMACEUTICALS, INC.: INVESTORS: PRESS RELEASES, "Cellegy Pharmaceuticals Receives FDA Nonapproval Letter for Fortigel," July 7, 2003, www.cellegy.com.	
		DELANOE et al., "Androgenisation of Female Partners of Men on Medroxyprogesterone Acetate/Percutaneous Testosterone Contraception," The Lancet (Feb 1984), p. 276.	
		DEMERY, A. "Contraception Masculine" Soins Gyn.-Obs.-Puer.-Ped., No. 72 (May 1987) pp. 33-38.	
		MARBURY et al., "Evaluation of the Pharmacokinetic Profiles of the New Testosterone Topical Gel Formulation, Testim(TM), Compared to AndroGel(R)," Biopharm. Drug Dispos., 24:115-120 (2003).	
		MORGAN et al., "Enhanced Skin Permeation of Sex Hormones with Novel Topical Spray Vehicles," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1213-1218.	
SAO		MORGAN et al., "Enhanced Transdermal Delivery of Sex Hormones in Swine with a Novel Topical Aerosol," J. Pharm. Science (1998) Vol. 87 No. 10, pp. 1219-1225.	

Examiner
SignatureDate
Considered

10/14/2003

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.
This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/088 (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Project (PTO-234), no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/046,454
Filing Date	October 19, 2001
First Named Inventor	DUDLEY, R.
Art Unit	1617
Examiner Name	JIANG, S.
Attorney Docket Number	01917581

Sheet 4 of 4

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
SJD		"PERCUTACRINE STRONG ANDROGENIC Testosterone" Percutacrine Androgenique Forte from VIDAL dictionary (1985).	✓
		POPE JR., et al., "Testosterone Gel Supplementation for Men with Refractory Depression: A Randomized, Placebo-Controlled Trial," Am. J. Psychiatry, 160(1): 105-111 (2003).	
		Protest Under 37 CFR 1.291(a) of U.S. Patent Application No. 09/651,777 dated August 20, 2002.	
SJD		SCHOOR, M., "Livening Up Libidos: Testosterone Patches Can Help Revive Women's Sex Drive," www.abcnews.com, September 6, 2000.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



RECEIVED
JUL 18 2003
TECH CENTER 1 of 34
581000/2900

Form PTO - 1449 (Modified)

FORM PTO-1449
(Modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
01917581

SERIAL NO.
10/046,454

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APPLICANT
R. Dudley

FILING DATE
October 19, 2001

GROUP
1617

(Use several sheets if necessary)

(37 CFR 1.98 (b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	PATENT NUMBER								PATENTEE	CLASS	SUB CLASS	FILING DATE
SAD	2	1	5	5	6	5	8	04/25/39	Herrman, et al.			
	3	0	6	8	1	8	8	12/11/62	Beste, et al.			
	3	2	1	8	2	8	3	11/16/65	Miller			
	3	8	8	7	6	9	9	06/03/75	Yolles			
	3	9	3	9	1	1	1	02/17/76	Schollenberger, et al.			
	4	0	0	9	2	5	4	02/22/77	Renold			
	4	0	8	3	9	7	3	04/11/78	Van der Vies			
	4	1	6	1	9	4	8	07/24/79	Bichon			
	4	4	4	7	5	6	2	05/08/84	Ivani			
	4	4	7	8	8	2	2	10/23/84	Haslam, et al.			
	4	6	3	1	1	8	8	12/23/86	Stoy, et al.			
	4	6	9	0	7	7	5	09/01/87	Schott, et al.			
	4	7	0	4	2	8	2	11/03/87	Campbell, et al.			
	4	7	2	5	4	3	9	02/16/88	Campbell, et al.			
	4	7	4	5	1	6	0	05/17/88	Churchill, et al.			
	4	7	6	7	6	2	7	08/30/88	Caldwell, et al.			
	4	7	8	0	3	2	0	10/25/88	Baker			
	4	7	8	8	0	6	2	11/29/88	Gale, et al.			
	4	9	2	0	2	0	3	04/24/90	Tang, et al.			
	4	9	4	6	8	7	0	08/07/90	Partain, III, et al.			
	4	9	8	1	6	9	6	01/01/91	Loomis, et al.			
	5	0	1	3	5	5	3	05/07/91	Southard, et al.			
	5	0	7	1	6	5	7	12/10/91	Oloff, et al.			
	5	1	5	2	9	9	7	10/06/92	Ebert, et al.			
	5	2	3	1	0	8	7	07/27/93	Thornfeldt			
	5	2	5	6	6	5	2	10/26/93	El-Rashidy			
	5	3	2	6	7	9	0	07/05/94	Thornfeldt			
	5	3	4	0	5	8	6	08/23/94	Pike, et al.			
	5	3	6	2	4	9	7	11/08/94	Yamada, et al.			
	5	4	4	6	0	7	0	08/29/95	Mantelle			
	5	4	6	0	8	2	0	10/24/95	Ebert, et al.			
	5	6	1	0	1	5	0	03/11/97	Labrie			
	5	6	2	9	0	2	1	05/13/97	Wright			
	5	6	4	1	5	0	4	06/24/97	Lee, et al.			
	5	6	4	3	8	9	9	07/01/97	Elias, et al.			
	5	6	4	8	3	5	0	07/15/97	DeLignieres			
	5	6	5	1	9	7	3	07/29/97	Moo-Young, et al.			
	5	6	5	4	3	3	7	08/05/97	Roentsch, et al.			
	5	6	5	6	2	8	6	08/12/97	Miranda, et al.			
	5	7	0	8	0	3	8	01/13/98	Davis			
	5	7	2	3	1	1	4	03/03/98	Thornfeldt, et al.			
	5	7	7	0	6	0	6	06/23/98	El Rashidy, et al.			
	5	7	1	6	6	3	8	02/10/98	Touitou			
	5	7	1	9	1	9	7	02/17/98	Kanios, et al.			
	5	7	7	6	9	2	3	07/07/98	Labrie			

SAD 10/14/03



RECEIVED

JUL 18 2003

TECH CENTER 1600/2900

SHEET 3 of 34

Form PTO-1449 (Modified)

FORM PTO-1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
01917581SERIAL NO.
10/046,454INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
R. DudleyFILING DATE
October 19, 2001GROUP
1617

(Use several sheets if necessary)

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

500		Yu, et al., <i>Transdermal Testosterone Administration in Hypogonadal Men: Comparison of Pharmacokinetics at Different Sites of Application and at the First and Fifth Days of Application</i> , J CLIN PHARMACOL, 37:1129-1138 (1997).
500		Yu, et al., <i>Testosterone Pharmacokinetics after Application of an Investigational Transdermal System in Hypogonadal Men</i> ; J CLIN PHARMACOL, 37:1139-1145 (1997).
		Testoderm, PHYSICIANS' DESK REFERENCE, Alza 517-520.
500		Cunningham, et al., <i>Testosterone Transdermal Delivery System</i> , PHARMACOLOGY, BIOLOGY, AND CLINICAL APPLICATIONS OF ANDROGENS ; 42:437-447 1996 Wiley-Liss, Inc.
		Carey, et al., <i>Transdermal Testosterone Treatment of Hypogonadal Men</i> , THE JOURNAL OF UROLOGY, Vol. 140, pp. 76-79, (July 1988).
		Bals-Pratsch, et al., <i>Substitution Therapy of Hypogonadal Men with Transdermal Testosterone Over One Year</i> , ACTA ENDOCRINOLOGICA (COPENH) 1988, 118: 7-13.
		Meikle, et al., <i>Androderm: A Permeation Enhanced Non-Scrotal Testosterone Transdermal System for the Treatment of Male Hypogonadism</i> , PHARMACOLOGY, BIOLOGY, AND CLINICAL APPLICATIONS OF ANDROGENS, 43:449-457, 1996 Wiley-Liss, Inc.
		Arver, et al., <i>Long-Term Efficacy and Safety of a Permeation-Enhanced Testosterone Transdermal System in Hypogonadal Men</i> , CLINICAL ENDOCRINOLOGY, 47: 727-737 (1997).
		Brooks, et al., <i>Pharmacokinetics of Testosterone in Hypogonadal Men After Transdermal Delivery: Influence of Dose</i> , J CLIN PHARMACOL 1996; 36:732-739.
		Cofrancesco, Jr., et al., <i>Transdermal Testosterone Delivery Systems</i> , THE ENDOCRINOLOGIST, Vol. 6, No. 3, pp. 207-213.
		Mazer, et al., <i>Enhanced Transdermal Delivery of Testosterone: A New Physiological Approach for Androgen Replacement in Hypogonadal Men</i> , JOURNAL OF CONTROLLED RELEASE, 19 (1992) 347-362.
500		Schurmeyer, et al, <i>Comparative Pharmacokinetic of Testosterone Enanthate and Testosterone Cyclohexanecarboxylate as Assessed by Serum and Salivary Testosterone Levels in Normal Men</i> , INTERNATIONAL JOURNAL OF ANDROLOGY, 7 (1984) 181-187.

500 10/14/03



RECEIVED
JUL 18 2003
SHEET 4 of 34
TECH CENTER 1600/2900

Form PTO-1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617
(37 CFR 1.98 (b))			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SAJ	Behre, et al., <i>Testosterone Buciclate (20 Aet-1) in Hypogonadal Men: Pharmacokinetics and Pharmacodynamics of the New Long-Acting Androgen Ester</i> , JOURNAL OF ENDOCRINOLOGY AND METABOLISM, Vol. 75, No. 5, pp. 1204-1210 (1992).
	Jockenhover, et al., <i>Pharmacokinetics and Pharmacodynamics of Subcutaneous Testosterone Implants in Hypogonadal Men</i> , CLINICAL ENDOCRINOLOGY, (1996) 45 61-71.
	<i>Sexual Dysfunction in the Male – Sexual Arousal Disorder</i> , THE MERCK MANUAL, Sixteenth Edition, Ch. 139, pp. 1575-1576 (1992).
	Weinbauer, et al., <i>Pharmacokinetics and Pharmacodynamics of Testosterone Enanthate and Dihydrotestosterone Enanthate in Non-Human Primates</i> , ACTA ENDOCRINOLOGICA (COPENH) 1990, 122, 4: 432-442.
	Bagatell, et al., <i>Effects of Endogenous Testosterone and Estradiol on Sexual Behavior in Normal Young Men</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 78, No. 3, pp. 711 (1994).
	Bancroft, <i>Endocrinology of Sexual Function</i> , CLINICS IN OBSTETRICS AND GYNAECOLOGY, Vol. 7, No. 2, August 1980, p. 253.
	Knussmann, et al., <i>Relations Between Sex Hormone Levels and Sexual Behavior in Men</i> , ARCHIVES OF SEXUAL BEHAVIOR, Vol. 15, No.5, p. 429 (1986).
	Kraemer, et al., <i>Orgasmic Frequency and Plasma Testosterone Levels in Normal Human Males</i> , ARCHIVES OF SEXUAL BEHAVIOR, Vol. 5, No. 2, p.125 (1976).
	Anderson, et al, <i>The Effects of Exogenous Testosterone on Sexuality and Mood of Normal Men</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 75, No. 6, p.1503 (1992).
	Tsitouras, <i>Effects of Age on Testicular Function</i> , ENDOCRINOLOGY AND METABOLISM CLINICS, Vol. 16, No. 4, p.1045-1059 (December 1987).
	Vermeulen, et al., <i>Long-Term Transdermal Dihydrotestosterone Therapy: Effects on Pituitary Gonadal Axis and Plasma Lipoproteins</i> , MATURITAS, 7 (1985) 281-287.
SAJ	Gooren, <i>Androgen Levels and Sex Functions in Testosterone-Treated Hypogonadal Men</i> , ARCHIVES OF SEXUAL BEHAVIOR, Vol. 16, No. 6, p.463-473 (1987).

SAJ 10/14/03



RECEIVED

JUL 18 2003

TECH CENTER 1600/2900 SHEET 5 of 34

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SEP	McClure, et al., <i>Hypogonadal Impotence Treated by Transdermal Testosterone</i> , UROLOGY, Vol. XXXVII, No. 3, pp. 224-228 (March 1991).
	Chemana, et al., <i>Percutaneous Absorption of 5α-dihydrotestosterone in Man II. Percutaneous Administration of 5α-dihydrotestosterone in Hypogonadal Men with Idiopathic Haemochromatosis; Clinical, Metabolic and Hormonal Effectiveness</i> , INTERNATIONAL JOURNAL OF ANDROLOGY, 5 (1982) 595-606.
	de Lignieres, <i>Transdermal Dihydrotestosterone Treatment of Andropause</i> , ANNALS OF MEDICINE 25: 235-241, 1993.
	Skakkebaek, et al., <i>Androgen Replacement with Oral Testosterone Undecanoate in Hypogonadal Men: A Double Blind Controlled Study</i> , CLINICAL ENDOCRINOLOGY (1981) 14, 49-61.
	Cunningham, et al., <i>Testosterone Replacement Therapy and Sleep-Related Erections in Hypogonadal Men</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 70, No. 3, 792-797.
	Rousseau, et al., <i>Inhibition of Steroid-Protein Interactions by Dicyclohexane Derivatives</i> , J STEROID BIOCHEM, Vol. 31, No. 4B, pp 691-697 (1988).
	Mooradian, et al., <i>Biological Actions of Androgens</i> , ENDOCRINE REVIEWS, Vol. 8, No. 1, pp 1-28 (1987).
	Mantzoros, et al., <i>Contribution of Dihydrotestosterone to Male Sexual Behaviour</i> , BRITISH MEDICAL JOURNAL, No. 6990, Vol. 310, pp 1289-1291 (May 20, 1995).
	Davidson, et al., <i>Hormonal Replacement and Sexuality in Men</i> , CLINICS IN ENDOCRINOLOGY AND METABOLISM, Vol. 11, No. 3, pp. 599-623 (November 1982).
	Hardy, et al., <i>Endocrine Assessment of Impotence - Pitfalls of Measuring Serum Testosterone Without Sex-Hormone-Binding Globulin</i> , POSTGRAD MED J (1994) 70, 836-837.
	Lewis, et al., <i>Serum 5α-Dihydrotestosterone and Testosterone Changes with Age in Man</i> , ACTA ENDOCRINOLOGICA, 82 (1976) 444-448.
SEP	Cunningham, et al., <i>Plasma Sex Hormone-Binding Globulin Levels Decrease During the Second Decade of Life Irrespective of Pubertal Status</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 58, No. 5, pp. 915-918 (1984).

SEP

10/14/03



Form PTO - 1449 (Modified)

FORM PTO-1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
01917581SERIAL NO.
10/046,454INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

APPLICANT

R. Dudley

FILING DATE
October 19, 2001GROUP
1617

(Use several sheets if necessary)

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

500		Morley, et al., <i>Longitudinal Changes in Testosterone, Luteinizing Hormone, and Follicle-Stimulating Hormone in Healthy Older Men</i> , METABOLISM, Vol. 46, No. 4 (April 1997), pp. 410-413.
		Damassa, et al., <i>Sex Hormone-Binding Globulin and Male Sexual Development</i> , NEUROSCIENCE AND BIOBEHAVIORAL REVIEWS, Vol. 19, No. 2, pp. 165-175 (1995).
		Behre, et al., <i>Long-Term Effect of Testosterone Therapy on Bone Mineral Density in Hypogonadal Men</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 82, No. 8, pp. 2389-1997.
		Leifke, et al., <i>Effects of Testosterone Replacement Therapy on Cortical and Trabecular Bone Mineral Density, Vertebral Body Area and Paraspinal Muscle Area in Hypogonadal Men</i> , EUROPEAN JOURNAL OF ENDOCRINOLOGY (1998) 138 51-58.
		Wang, et al., <i>Comparative Pharmacokinetics of Three Doses of Percutaneous Dihydrotestosterone Gel in Healthy Elderly Men - A Clinical Research Center Study</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 83, No. 8, pp 2749-2757 (1998).
		Dobs, et al., <i>Pharmacokinetics, Efficacy and Safety of a Permeation-Enhanced Testosterone Transdermal System in Comparison with Bi-Weekly Injections of Testosterone Enanthate for the Treatment of Hypogonadal Men</i> , THE JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 84, No. 10, pp. 3469-3478 (1999).
		Snyder, et al., <i>Effect of Testosterone Treatment on Bone Mineral Density in Men Over 65 Years of Age</i> , THE JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 84, No. 6, pp. 1966-1972 (1999).
		Parker, et al., <i>Experience with Transdermal Testosterone Replacement Therapy for Hypogonadal Men</i> , CLINICAL ENDOCRINOLOGY (1999) 50, 57-62.
		Behre, et al., <i>Long-Term Substitution Therapy of Hypogonadal Men with Transscrotal Testosterone Over 7-10 Years</i> , CLINICAL ENDOCRINOLOGY (1999) 50, 629-635.
		Behre, et al., <i>Intramuscular Injection of Testosterone Undecanoate for the Treatment of Male Hypogonadism: Phase I Studies</i> , EUROPEAN JOURNAL OF ENDOCRINOLOGY (1999) 140 414-419.
500		Bhasin, et al., <i>Therapeutic Perspective - Issues in Testosterone Replacement in Older Men</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 83, No. 10, pp. 3435-3448 (1998)

500 10/14/03



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

5910	McClellan, et al., <i>Transdermal Testosterone</i> , ADIS NEW DRUG PROFILE - DRUGS, 1998 Feb. 55(2): 253-258.
	Abitbol, et al., <i>Sex Hormones and the Female Voice</i> , J VOICE, 1999 Sep; 13(3): 424-46.
	Almeida, <i>Sex Playing with the Mind. Effects of Oestrogen and Testosterone Mood and Cognition</i> , ARQ NEUROPSIQUIATR, 1999 Sept; 57(3A): 701-6.
	Angold, et al., <i>Pubertal Changes in Hormone Levels and Depression in Girls</i> , PSYCHOL MED 1999 Sep; 29(5): 1043-53.
	Barrett-Conner, et al., <i>Cognitive Function and Endogenous Sex Hormones in Older Women</i> , J AM GERIATR SOC, 1999 Nov; 47(11): 1289-93.
	Barrett-Conner, et al., <i>A Two-Year, Double-Blind Comparison of Estrogen-Androgen and Conjugated Estrogens in Surgically Menopausal Women. Effects Bone Mineral Density, Symptoms and Lipid Profiles</i> , J REPROD MED, 1999 Dec; 44(12): 1012-20.
	Drake, et al., <i>Associations Between Circulating Sex Steroid Hormones and Cognition in Normal Elderly Women</i> , NEUROLOGY, 2000 Feb; 54(3): 599-603.
	Tuiten, et al., <i>Time Course of Effects of Testosterone Administration on Sexual Arousal in Women</i> , ARCH GEN PSYCHIATRY, 2000 Feb; 57(2): 149-53.
	Gonzalez-Sagrado, et al., <i>Reference Values and Methods Comparison of a New Testosterone Assay on the AxSYM System</i> , CLIN BIOCHEM, 2000 Apr; 33(3): 175-9.
	Floter, et al., <i>Administration of Testosterone Undecanoate in Postmenopausal Women: Effects on Androgens, Estradiol, and Gonadotrophins.</i> , MENOPAUSE, 2000 Jul-Aug; 7(4): 251-6.
	Javanbakht, et al., <i>Pharmacokinetics of a Novel Testosterone Matrix Transdermal System in Healthy, Premenopausal Women and Women Infected with the Human Immunodeficiency Virus</i> , J CLIN ENDOCRINOL METAB, 2000 Jul; 85(7): 2395-401.
	Shifren, et al., <i>Transdermal Testosterone Treatment in Women with Impaired Sexual Function After Oophorectomy</i> . THE NEW ENGLAND JOURNAL OF MEDICINE, Sept. 7, 2000, Vol. 343, No. 10, 682-688.
5910	<i>Sex, Hormones, and Hysterectomies</i> , THE NEW ENGLAND JOURNAL OF MEDICINE, Sept. 7, 2000 - Vol. 343, No. 10, 730-731.

5910 10/14/03

**RECEIVED**

JUL 18 2003

SHEET 8 of 34

TECH CENTER 1600/2900

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		ENDO 99: Testosterone Patch Effective for Diminished Sexual Function in Surgically Menopausal Women, DOCTOR'S GUIDE TO THE INTERNET, http://www.docguide.com , June 15, 1999.
597		C. Wang, et al., Sublingual Testosterone Replacement Improves Muscle Mass and Strength, Decreases Bone Resorption, and Increases Bone Formation Markers in Hypogonadal Men - A Clinical Research Center Study, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 81, No. 10, pp. 3654-3662 (1996).
		C. Wang, et al., Testosterone Replacement Therapy Improves Mood in Hypogonadal Men - A Clinical Research Center Study, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 81, No. 10, pp. 3578-3583 (1996).
		Meikle, et al., Pharmacokinetics and Metabolism of a Permeation-Enhanced Testosterone Transdermal System in Hypogonadal Men: Influence of Application Site - A Clinical Research Center Study, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 81, No. 5, pp. 1832-1840 (1996).
		Salehian, et al., Pharmacokinetics, Bioefficacy, and Safety of Sublingual Testosterone Cyclodextrin in Hypogonadal Men: Comparison to Testosterone Enanthate - A Clinical Research Center Study, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 80, No. 12, pp. 3567-75.
		Bhasin, Clinical Review 34 - Androgen Treatment of Hypogonadal Men, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 74, No. 6, pp. 1221-1225 (1992).
		Stuenkel, et al, Sublingual Administration of Testosterone-Hydroxypropyl- β -Cyclodextrin Inclusion Complex Simulates Episodic Androgen Release in Hypogonadal Men, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 72, No.5, pp. 1054-1059 (1991).
		Handelsman, et al., Pharmacokinetics and Pharmacodynamics of Testosterone Pellets in Man, JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 70, No. 1., pp. 216-222 (1990).
597		Sherwin, et al., The Role of Androgen in the Maintenance of Sexual Functioning in Oophorectomized Women, PSYCOSOMATIC MEDICINE, 49: 397-409 (1987).

597 10/14/03



RECEIVED

JUL 18 2003

TECH CENTER 1600/2900

SHEET 9 of 34

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

520	Kuhn, et al., <i>Traitement Androgenique Percutane des Hypogonadismes Masculins. Efficacite Comparee de la Testosterone et d la Dihydrotestosterone: Etude de 40 Observations</i> , CONTRACEPTION-FERTILITE-SEXUALITE, Vol. 14, No. 11, pp 1031-1036 (1986).
	Wang, et al., <i>Pharmacokinetics of Transdermal Testosterone Gel in Hypogonadal Men: Application of Gel at One Site Versus Four Sites: A General Clinical Research Center Study</i> , THE JOURNAL OF ENDOCRINOLOGY AND METABOLISM, Vol. 85, No. 3, pp 964-969 (2000).
	Marin, et al., <i>Androgen Treatment of Middle-Aged, Obese Men: Effects on Metabolism, Muscle and Adipose Tissues</i> , ANDROGENS, MUSCLE AND ADIPOSE TISSUE IN MEN, Vol. 1, NO. 6, pp.329-336 (1992).
	Morley, et al., <i>Androgen Deficiency in Aging Men: Role of Testosterone Replacement Therapy</i> , J. LAB CLIN MED, Vol. 135, No. 5, pp. 370-370 (2000)
	Jaffe, et al., <i>Effect of 5-Alpha-Reductase Inhibition on Sex-Hormone-Binding Globulin in Elderly Men</i> , HORM RES, 1994;41:215-217.
	Sherwin, <i>Affective Changes with Estrogen and Androgen Replacement Therapy in Surgically Menopausal Women</i> , JOURNAL OF AFFECTIVE DISORDERS, 14 (1988) 177-187.
	Sherwin, <i>Estrogen and/or Androgen Replacement Therapy and Cognitive Functioning in Surgically Menopausal Women</i> , PSYCHONEUROENDOCRINOLOGY, Vol. 13, NO. 4, pp. 345-357 (1988).
	Sherwin, <i>Sex Hormones and Psychological Functioning in Postmenopausal Women</i> , EXPERIMENTAL GERONTOLOGY, Vol. 29, Nos. 3/4, pp. 423-430 (1994).
	Need, et al., <i>Double-Blind Placebo-Controlled Trial of Treatment of Osteoporosis with the Anabolic Nandrolone Decanoate</i> , OSTEOPOROSIS INT (1993) Supl. 1: S218-222.
	Raisz, et al., <i>Comparison of the Effects of Estrogen Alone and Estrogen Plus Androgen on Biochemical Markers of Bone Formation and Resorption in Postmenopausal Women</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 81, No. 1, pp. 37-43 (1996).
	Cashdan, <i>Hormones, Sex and Status in Women</i> , HORMONES AND BEHAVIOR, 29, 354-366 (1995).
520	Morrison, et al, <i>Androgens in the Elderly: Will Androgen Replacement Therapy Improve Mood, Cognition, and Quality of Life in Aging Men and Women</i> , PSYCHOPHARMACOLOGY BULLETIN, 33(2):293-296 (1997).

520 10/14/03



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SEP	Gruber, et al., <i>Effect of Percutaneous Androgen Replacement Therapy on Body Composition and Body Weight in Postmenopausal Women</i> , MATURITAS 29 (1998) 253-259.
	Buckler, et al. <i>The Effects of Low-Dose Testosterone Treatment on Lipid Metabolism, Clotting Factors and Ultrasonographic Ovarian Morphology in Women</i> , CLINICAL ENDOCRINOLOGY (1997) 49, 173-178.
	Douchi, et al., <i>Serum Androgen Levels and Muscle Mass in Women with Polycystic Ovary Syndrome</i> , OBSTETRICS & GYNECOLOGY, Vol. 94, No. 3, pp. 337-340 (1999).
	Vermeulen, et al., <i>Long-Term Transdermal Dihydrotestosterone Therapy: Effects on Pituitary Gonadal Axis and Plasma Lipoproteins</i> , MATURITAS, 7 (1985) 281-287.
	Davidson, et al., <i>Hormonal Changes and Sexual Function in Aging Men</i> , JOURNAL OF CLINICAL ENDOCRINOLOGY AND METABOLISM, Vol. 57, No. 1, pp. 71-77 (1983)
	Klugo, et al., <i>Response of Micropenis to Topical Testosterone and Gonadotropin</i> , , THE JOURNAL OF UROLOGY, Vol. 119, May, pp. 667-668. (1978).
	Basson, et al., <i>Androgen Replacement for Women</i> , CANADIAN FAMILY PHYSICIAN, Vol. 45: September 1999, pp. 2100-2107.
	Persky, et al., <i>The Relation of Plasma Androgen Levels to Sexual Behaviors and Attitudes of Women</i> , PSYCHOSOMATIC MEDICINE, Vol. 44, No. 4 (Sept. 1982).
	de Lignieres, et al., <i>Treatment of Male Hypogonadism by Topical Administration of Androgens</i> ,
	Carlstrom, et al., <i>Relationship Between Serum Testosterone and Sex Hormone-Binding Globulin in Adult Men with Intact or Absent Gonadal Function</i> , INTERNATIONAL JOURNAL OF ANDROLOGY, 1990, 13, pp. 67-73.
	Moller, et al., <i>Sex Hormone-Binding Globulin Mediates Prostate Androgen Receptor Action via a Novel Signaling Pathway</i> , ENDOCRINOLOGY, 1998 Jan; 139(1):213-8.
	Mantzoros, et al., <i>Serum Steroids in Relation to Benign Prostatic Hyperplasia</i> , ONCOLOGY, 1997 Nov-Dec; 54(6):497-501.
SEP	Nakhla, et al., <i>Stimulation of Prostate Cancer Growth by Androgens and Estrogens Through the Intermediacy of Sex Hormone-Binding Globulin</i> , ENDOCRINOLOGY, 1996 Oct; 137(10): 4126-9.

SEP 10/14/03



Form PTO - 1449 (Modified)

FORM PTO-1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEATTY. DOCKET NO.
01917581SERIAL NO.
10/046,454INFORMATION DISCLOSURE
STATEMENT BY APPLICANTAPPLICANT
R. DudleyFILING DATE
October 19, 2001GROUP
1617

(Use several sheets if necessary)

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

See	Gann, et al., <i>Prospective Study of Sex Hormone Levels and Risk of Prostate Cancer</i> , J NATL CANCER INST, 1996 Aug 21; 88(16): 1118-26.
	Liao, <i>Androgen Action: Molecular Mechanism and Medical Application</i> , J FORMOS MED ASSOC, 1994 Sep; 93(9): 741-51.
	Shirai, et al., <i>Effects of Testosterone, Dihydrotestosterone and Estrogen on 3,2'-Dimethyl-4-Aminobiphenyl-Induced Rat Prostate Carcinogenesis</i> , INT J CANCER, 1994 Apr 15; 57(2):224-8.
	Isaacs, <i>Etiology of Benign Prostatic Hyperplasia</i> , EUR UROL, 1994; 25 Suppl 1:6-9.
	Denis, <i>Future Implications for the Management of Benign Prostatic Hyperplasia</i> , EUR UROL, 1994; 25 Suppl 1:29-34.
	Nevalainen, et al., <i>Hormone Regulation of Human Prostate in Organ Culture</i> , CANCER RES, 1993 Nov 1; 53(21):5199-207.
	Alivizatos, et al., <i>Update of Hormonal Treatment in Cancer of the Prostate</i> , ANTICANCER DRUGS, 1993 Jun; 4(3):301-9.
	Geller, <i>Basis for Hormonal Management of Advanced Prostate Cancer</i> , CANCER, 1993 Feb 1; 71(3 Suppl): 1039-45.
	Geller, <i>Nonsurgical Treatment of Prostatic Hyperplasia</i> , CANCER, 1992 Jul 1; 70(1 Suppl): 339-45.
	Geller, <i>Pathogenesis and Medical Treatment of Benign Prostatic Hyperplasia</i> , PROSTATE SUPPL, 1989; 2:95-104.
	Isaacs, et al., <i>Etiology and Disease Process of Benign Prostatic Hyperplasia</i> , PROSTATE SUPPL, 1989; 2:33-50.
	Bruun, et al., <i>Dihydrotestosterone Measured in Core Biopsies from Prostatic Tissues</i> , AM J CLIN ONCOL, 1988; 11 Suppl 2:S27-9.
	Petrangeli, et al., <i>Effects of Two Different Medical Treatments on Dihydrotestosterone Content and Androgen Receptors in Human Benign Prostatic Hyperplasia</i> , J STEROID BIOCHEM, 1988; 30(1-6): 395-9.
	Voigt, et al., <i>The Role of Tissue Steroids in Benign Hyperplasia and Prostate Cancer</i> , UROLOGE [A], 1987 Nov; 26(6):349-57.
	Pollard, et al., <i>Dihydrotestosterone Does Not Induce Prostate Adenocarcinoma in L-W Rats</i> , PROSTATE, 1987; 10(4):325-31.
	Petrow, <i>The Dihydrotestosterone (DHT) Hypothesis of Prostate Cancer and its Therapeutic Implications</i> , PROSTATE, 1986; 9(4): 343-61.
See	Geller, et al., <i>DHT in Prostate Cancer Tissue - a Guide to Management and Therapy</i> , PROSTATE, 1985; 6(1):19-25.

See 10/14/03



RECEIVED

JUL 18 2003

TECH CENTER 1600/2900 SHEET 12 of 34

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617
(37 CFR 1.98 (b))			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

590	Drafta, et al., <i>The Effects of Endocrine Therapy on Plasma Steroids in Prostatic Carcinoma Patients</i> , ENDOCRINOLOGIE, 1984 Jul-Sep; 22(3): 191-7.
	Karr, et al., <i>Induction of Benign Prostatic Hypertrophy in Baboons</i> , UROLOGY, 1984 Mar; 23(3): 276-89.
	Ewing, et al., <i>Dihydrotestosterone Concentration of Beagle Prostatic Tissue: Effect of Age and Hyperplasia</i> , ENDOCRINOLOGY, 1983 Dec; 113(6): 2004-9.
	Stahl, et al., <i>Effects of Tamoxifen on the Levels of Luteinizing Hormone (LH), Follicle Stimulating Hormone (FSH), Prolactin (PRL), 17 beta-oestradiol (E2), Total and Free Testosterone (T) and Total and Free Dihydrotestosterone (DHT) in blood of Patients with Benign Prostatic Hyperplasia</i> , EXP CLIN ENDOCRINOL, 1983 Jul; 82(1): 21-8.
	Meikle, et al., <i>Familial Prostatic Cancer Risk and Low Testosterone</i> , J CLIN ENDOCRINOL METAB, 1982 Jun; 54(6): 1104-8.
	Wilson, <i>The Pathogenesis of Benign Prostatic Hyperplasia</i> , AM J MED, 1980 May; 68(5): 745-56.
	Sidh, et al., <i>Adenocarcinoma of Prostate: Role of 17beta-Estradiol and 5alpha-Dihydrotestosterone Binding Proteins</i> , UROLOGY, 1979 Jun; 13(6): 597-603.
	Bartsch, et al., <i>Sex Hormone Binding Globulin Binding Capacity, Testosterone, 5alpha-Dihydrotestosterone, Oestradiol and Prolactin in Plasma of Patients with Prostatic Carcinoma under Various Types of Hormonal Treatment</i> , ACTA ENDOCTRINOL (COPENH), 1977 Jul; 85(3): 650-64.
	Arver, et al., <i>Improvement of Sexual Function in Testosterone Deficient Men Treated for 1 Year with a Permeation Enhanced Testosterone Transdermal System</i> , J UROL, 1996 May; 155(5): 1604-8.
	Gooren, <i>A Ten-Year Safety Study of the Oral Androgen Testosterone Undecanoate</i> , 1994 May-Jun; 15(3):212-5.
	Mermall, et al., <i>Temporal (Circadian) and Functional Relationship between Pro Specific Antigen and Testosterone in Healthy Men</i> , UROLOGY, 1995 Jul; 46(1): 45-53.
	Vijayakumar, et al., <i>Results of a Study to Correlate Serum Prostate Specific antigen Reproductive Hormone Levels in Patients with Localized Protate Cancer</i> , J NATL MED ASSOC, 1995 Nov; 87(11): 813-9.
590	Berner, et al., <i>Pharmacokinetic Characterisation of Transdermal Delivery System</i> , CLIN PHARMACOKINET, 1994 Feb; 26(2): 121-34.

590 10/14/03



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SP	Behre, et al., <i>Prostate Volume in Testosterone-Treated and Untreated Hypogonadal Men in Comparison to Age-Matched Normal Controls</i> , CLIN ENDOCRINOL (OXF), 1994 Mar; 40(3): 341-9.
	Akimoto, et al., <i>Relationship Between Diurnal Rhythm of Serum Testosterone and Prostatic Markers (PSA and PAP) in Untreated Prostate Cancer</i> , UROLOGY, 1994 Mar; 43(3): 337-41.
	Bhasin, et al., <i>A Biodegradable Testosterone Microcapsule Formulation Providing Uniform Eugonadal Levels of Testosterone for 10-11 Weeks in Hypogonadal Men</i> , J CLIN ENDOCRINOL METAB, 1992 Jan; 74(1): 75-83.
	Place, et al., <i>Transdermal Delivery of Testosterone with Testoderm to Provide Normal Circadian Pattern of Testosterone</i> , ANN NY ACAD SCI, 1991; 618:441-9.
	Conway, et al., <i>Randomized Clinical Trial of Testosterone Replacement Therapy in Hypogonadal Men</i> , INT J ANDROL, 1988 Aug; 11(4): 247-64.
	Tenover, et al., <i>Age-Related Alterations in the Circadian Rhythms of Pulsatile Luteinizing Hormone and Testosterone Secretion in Healthy Men</i> , J GERONTOL, 1988 Nov; 43(6): M163-9.
	Cunningham, et al., <i>Testosterone Replacement with Transdermal Therapeutic System, Physiological Serum Testosterone and Elevated Dihydrotestosterone Levels</i> , JAMA, 1989 May 5; 261(17): 2525-30.
	Plymate, et al., <i>Circadian Variation in Testosterone, Sex Hormone-Binding Globulin and Calculated Non-Sex Hormone-Binding Globulin Bound Testosterone in Healthy Young and Elderly Men</i> , J ANDROL, 1989 Sep-Oct; 10(5): 366-71.
	Meikle, et al., <i>Prostate Size in Hypogonadal Men Treated with Nonscrotal Permeation-Enhanced Testosterone Transdermal System</i> , UROLOGY, 1997 Feb; 49(2):191-6.
	Kuhn, et al., <i>Effects of 10 Days Administration of Percutaneous Dihydrotestosterone on the Pituitary-Testicular Axis in Normal Men</i> , J CLIN ENDOCRINOL METAB, 1984 Feb; 58(2): 231-5.
	Bals-Pratsch, et al., <i>Transdermal Testosterone Substitution Therapy for Male Hypogonadism</i> , LANCET, 1986 Oct 25; 2(8513): 943-6.
	Ahmed, et al., <i>Transdermal Testosterone Therapy in the Treatment of Male Hypogonadism</i> , J CLIN ENDOCRINOL METAB, 1988 Mar; 66(3): 546-51.
SP	Nilas, et al., <i>Bone Mass and its Relationship to Age and the Menopause</i> , J CLIN ENDOCRINOL METAB, 1987 Oct; 64(4): 697-702.



Form PTO-1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SAJ	Chakravarti, et al., <i>Endocrine Changes and Symptomatology After Oophorectomy in Premenopausal Women</i> , BR J OBSTET GYNAECOL, 1977 Oct; 84(10): 769-75.
	Persky, et al., <i>Plasma Testosterone Level and Sexual Behavior of Couples</i> , ARCH SEX BEHAV, 1978 May; 7(3): 157-73.
	Schreiner-Engel, et al., <i>Sexual Arousability and the Menstrual Cycle</i> , PSYCHOSOM MED 1981 Jun; 43(3): 199-214.
	Alexander, et al., <i>Sex Steroids, Sexual Behavior, and Selection Attention for Erotic Stimuli in Women Using Oral Contraceptives</i> , PSYCHONEUROENDOCRINOLOGY, 1993; 18(2): 91-102.
	Leiblum, et al., <i>Vaginal Atrophy in the Postmenopausal Woman. The Important Sexual Activity and Hormones</i> , JAMA, 1983 Apr 22-29;249(16): 2195-8.
	Bancroft, et al., <i>Mood, Sexuality, Hormones, and the Menstrual Cycle. III. Sexual. and the Role of Androgens.</i> , PSYCHOSOM MED, 1983 Dec; 45(6): 509-16.
	Burger, et al., <i>The Management of Persistent Menopausal Symptoms with Oestradiol-Testosterone Implants: Clinical, Lipid and Hormonal Results</i> , MATURITAS, 1984 Dec; 6(4): 351-8.
	Sherwin, et al., <i>Androgen Enhances Sexual Motivation in Females: a Prospective Crossover Study of Sex Steroid Administration in the Surgical Menopause</i> , PSYCHOSOM MED, 1985 Jul-Aug; 47(4): 339-51.
	McCoy, et al., <i>A Longitudinal Study of the Effects of Menopause on Sexuality</i> , MATURITAS, 1985 Sep; 7(3): 203-10.
	Morris, et al., <i>Marital Sex Frequency and Midcycle Female Testosterone</i> , ARCH SEX BEHAV, 1987 Feb; 16(1):27-37.
	Sherwin, et al., <i>Postmenopausal Estrogen and Androgen Replacement and Lipoprotein Lipid Concentrations</i> , AM J OBSTET GYNECOL, 1987 Feb; 156(2): 414-9.
	Burger, et al., <i>Effect of Combined Implants of Oestradiol and Testosterone on in Postmenopausal Women</i> , BR MED J (CLIN RES ED), 1987 Apr 11; 294-(6577): 936-7.
SAJ	Mazer, <i>New Clinical Applications of Transdermal Testosterone Delivery in Men and Women</i> , J CONTROLLED RELEASE, 2000 Mar 1; 65(1-2): 303-15.

SAJ 10/14/03



RECEIVED

JUL 18 2003

SHEET 15 of 34
TECH CENTER 1600/2900

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SAO	Dobs, <i>Pharmacokinetics, Efficacy, and Safety of a Permeation-Enhanced Testosterone Transdermal System in Comparison with Bi-Weekly Injections of Testosterone Enanthate for the Treatment of Hypogonadal Men</i> , J CLIN ENDOCRINOL METAB, 1999 Oct; 84(10): 3469-78.
SAO	<i>Testosterone Gel May Help Men with Low Sex Drive</i> , THE MEDICAL LETTER ON DRUGS AND THERAPEUTICS, Vol. 42 (Issue 1080), pp. 49-52 (June 12, 2000).
	<i>Testosterone Gel May Help Men with Low Sex Drive</i> , WRAL ONLINE. http://www.wral-tv.com/features/healthteam/1997/0814-tgel/ .
SAO	Masi, <i>Sex Hormones and Rheumatoid Arthritis: Cause or Effect Relationships in a Complex Pathophysiology?</i> , CLIN EXP RHEUMATOL, 1995 Mar-Apr; 13(2): 227-40.
	Davis, et al., <i>Testosterone Enhances Estradiol's Effects on Postmenopausal Bone Density and Sexuality</i> , MATURITAS, 1995 Apr; 21(3): 227-36.
	Schreiner-Engel, et al., <i>Low Sexual Desire in Women: the Role of Reproductive Hormones</i> , HORM BEHAV, 1989 Jun; 23(2): 221-34.
	Kirschner, et al., <i>Androgen-Estrogen Metabolism in Women with Upper Body Versus Lower Body Obesity</i> , J CLIN ENDOCRINOL METAB, 1990 Feb; 70(2): 473-9.
	Alexander, et al., <i>Testosterone and Sexual Behavior in Oral Contraceptive Users and Nonusers: a Prospective Study</i> , HORM BEHAV, 1990 Sep; 24(3): 388-402.
	Studd, et al., <i>The Relationship Between Plasma Estradiol and the Increase in Density in Postmenopausal Women After Treatment with Subcutaneous Hormone Implants</i> , AM J OBSTET GYNECOL, 1990 Nov; 163(5 Pt 1): 1474-9.
	Myers, et al., <i>Effects of Estrogen, Androgen, and Progestin on Sexual Psychophysiology and Behavior in Postmenopausal Women</i> , J CLIN ENDOCRINOL METAB, 1990 Apr; 70(4): 1124-31.
	Gouchie, et al., <i>The Relationship Between Testosterone Levels and Cognitive Ability Patterns</i> , PSYCHONEUROENDOCRINOLOGY, 1991; 16(4): 323-34.
	Garnett, et al., <i>A Cross-Sectional Study of the Effects of Long-Term Percutaneous Hormone Replacement Therapy on Bone Density</i> , OBSTET GYNECOL, 1991 Dec; 78(6): 1002-7.
SAO	Eriksson, et al., <i>Serum Levels of Androgens are Higher in Women with Premenstrual Irritability and Dysphoria than in Controls</i> , PSYCHONEUROENDOCRINOLOGY, 1992 May-Jul; 17(2-3): 195-204.

SAO 19/4/03



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

500	Garnett, et al., <i>The Effects of Plasma Estradiol Levels on Increases in Vertebral Femoral Bone Density Following Therapy with Estradiol and Estradiol with Testosterone Implants</i> , OBSTET GYNECOL, 1992 Jun; 79(6): 968-72.
500	Savvas, et al., <i>Increase in Bone Mass after One Year of Percutaneous Oestradiol Testosterone Implants in Post-Menopausal Women Who Have Previously Received Long-Term Oral Oestrogens</i> , BR J OBSTET GYNAECOL, 1992 Sep; 99(9): 757-60.
	Dr. N's Menopause & Hysterectomy-Resource Page, http://www.menopausehysterectomy.com/methods.htm
	Testosterone, PREVENTIVE MEDICINE CLINIC OF MONTEREY, http://www.wellnessmd.com/testo.html .
	Product Information - Testoderm TTS, PHYSICIANS' DESK REFERENCE, Alza/517-520
500	Kuhn, et al., <i>Gynecomastia: Effect of Prolonged Treatment with Dihydrotestosterone by the Percutaneous Route</i> , PRESSE MED, 1983 Jan 8; 12(1): 21-5.
	SEPA TESTOSTERONE TRANSDERMAL GEL RECEIVES APPLICATION BY FDA, DOCTOR'S GUIDE GLOBAL EDITION, http://pslggroup.com/dg/123aa.htm .
500	Press Release - 10/21/99 -- MacroChem Awarded U.S. Patent Covering Transdermal Hormone Replacement Incorporating Proprietary SEPA® Technology and Hormonally Active Drugs Such as Testosterone, Estradiol and Progesterone; http://www.mchm.com/press/pr24.asp
	AndrosteDERM, http://www.gethuge.net/androderm1.htm .
	Male Hormone Patch Approved, NUPHARM, http://www.nupharm.com/malehorm.htm
	SmithKline Beecham's New 5 mg Androderm Testosterone Transdermal System Now Available; INTERNATIONAL Association of Physicians in AIDS Care; http://www.iapac.org/clinmgt/compnews/sb061297.html .
	Treatments, IMPOTENCE WORLD ASSOCIATION, http://www.impotenceworld.org/treatment.htm .
	Andro-Gel, NETRITION, http://www.netrition.com/andro_gel_page.html .
	Prospectus - Cellegy Pharmaceuticals, Inc., OPPENHEIMER & CO., 1997.
	Cellegy Pharmaceuticals Market Opportunities, CELLEGY PHARMACEUTICALS, INC., http://www.cellegy.com/corp/market.html .

500 10/14/03



Form PTO - 1449 (Modified)

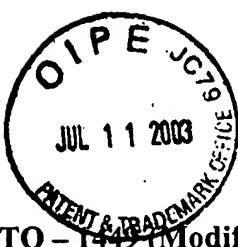
FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SAD		Itoh, et al., <i>The Assessment of Bioavailable Androgen Levels from the Serum Free Testosterone Level</i> , NIPPON NAIBUNPI GAKKAI ZASSHI, 1991 Jan 20; 67(1): 23-22
		Gaidano, et al., <i>Dynamics of the Binding Capacity of Plasma Sex Hormone Binding Globulin (SHBG) for Testosterone and Dihydrotestosterone During Puberty</i> , CLIN CHIM ACTA, 1980 Jan 15; 100(2): 91-97.
		Zmuda, et al., <i>Exercise Increases Serum Testosterone and Sex Hormone-Binding Globulin Levels in Older Men</i> , METABOLISM, 1996 Aug; 45(8): 935-939.
		Wang, et al., <i>Salivary Testosterone in Men: Further Evidence of a Direct Correlation with Free Serum Testosterone</i> , J CLIN ENDOCRINOL METAB, 1981 Nov; 53(5): 1021-1024.
		Fahrner, et al., <i>Effects of Endurance Exercise on Free Testosterone Concentration and the Binding Affinity of Sex Hormone Binding Globulin (SHBG)</i> , INT J SPORTS MED, 1998 Jan; 19(1): 12-15.
		Masters, et al., <i>Investigation of Sex-Hormone Binding Globulin Interference in Direct Radioimmunoassays for Testosterone and Estradiol</i> , CLIN CHEM, 1989 Jun; 35(6): 979-984.
		Pirke, et al., <i>Age Related Changes and Interrelationships Between Plasma Testosterone, Oestradiol and Testosterone-Binding Globulin in Normal Adult Males</i> , ACTA ENDOCRINOL (COPENH), 1973 Dec; 74(4): 792-800.
		Lewis, et al., <i>Proceedings: Age-Related Changes in Serum 5alpha-dihydrotestosterone and Testosterone in Normal Men</i> , J ENDOCRINOL, 1975 Nov; 67(2): 15P.
		Belgorosky, et al., <i>Dynamics of SHBG Response to Testosterone. Implications Upon the Immediate Biological Effect of Sex Hormones</i> , J STEROID BIOCHEM, 1983 Jun; 18(6): 783-787.
		Longcope, et al., <i>Androgens, Estrogens, and Sex Hormone-Binding Globulin in Middle-Aged Men</i> , J CLIN ENDOCRINOL METAB, 1990 Dec; 71(6): 1442-1446.
		Willemse, et al., <i>No Change in Plasma Free Testosterone Ratio and Plasma Sex Hormone-Binding Globulin Concentration During hCG Stimulation</i> , J CLIN ENDOCRINOL METAB, 1984 Jun; 58(6): 1193-1196.
	SAD	Valero-Politi, et al., <i>Annual Rhythmic Variations of Folitropin, Lutropin, Testosterone and Sex-Hormone-Binding Globulin in Men</i> , CLIN CHIM ACTA, 1998 Mar 9; 271(1): 57-71.

SAD 10/14/03

**RECEIVED**

JUL 18 2003

TECH CENTER 1600/2900 SHEET 18 of 34

Form PTO - 1449 (Modified)

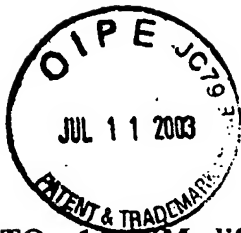
FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

<i>SPD</i>	Valero-Politi, et al., <i>Daily Rhythmic and Non-Rhythmic Variations of Follitropin, Lutropin, Testosterone, and Sex-Hormone-Binding Globulin in Men</i> , EUR J CLIN CHEM CLIN BIOCHEM, 1996 Jun; 34(6): 455-462.
	Kasper, et al., <i>Development, Progression, and Androgen-Dependence of Prostate Tumors in Probasin-Large T Antigen Transgenic Mice: a Model for Prostate Cancer</i> , LAB INVEST, 1998 Mar; 78(3): 319-333.
	Boots, et al., <i>Measurement of Total Serum Testosterone Levels Using Commercially Available Kits: High Degree of Between-Kit Variability</i> , FERTIL STERIL, 1988 Feb; 69(2): 286-292.
	Belgorosky, et al., <i>Progressive Decrease in Serum Sex Hormone-Binding Globulin from Infancy to Late Prepuberty in Boys</i> , J CLIN ENDOCRINOL METAB, 1986 Aug; 63(2): 510-512.
	Holownia, et al., <i>A Clinical Evaluation of a Direct Radioimmunoassay of Testosterone</i> , CLIN CHIM ACTA, 1993 Jan 31; 214(1): 31-43.
	Boyle, et al., <i>Serum Testosterone Measurements</i> , AM J CLIN PATHOL, 1984 Jun; 81(6): 754,761.
	Leinonen, et al., <i>Serum Sex Hormone Binding Globulin and Testosterone Binding After Estradiol Administration, Castration, and Their Combination in Men with Prostatic Carcinoma</i> , INVEST UROL, 1979 Jul; 17(1): 24-27.
	Winters, et al., <i>Serum LH Concentrations in Hypogonadal Men During Transdermal Testosterone Replacement Through Scrotal Skin: Further Evidence that Ageing Enhances Testosterone Negative Feedback. The Testoderm Study Group</i> , CLIN ENDOCRINOL (Oxf) 1997 Sep; 47(3): 317-322.
	Meikle, et al., <i>Enhanced Transdermal Delivery of Testosterone Across Nonscrotal Skin Produces Physiological Concentrations of Testosterone and Its Metabolites in Hypogonadal Men</i> , J CLIN ENDOCRINOL METAB, 1992 Mar; 74(3): 623-628.
	Winters, <i>The Gonadotropin-Suppressive Activity of Androgen is Increased in Elderly Men</i> , METABOLISM, 1984 Nov; 33(11): 1052-1059.
	Tenover, et al., <i>The Effects of Aging in Normal Men on Bioavailable Testosterone and Luteinizing Hormone Secretion: Response to Clomiphene Citrate</i> , J CLIN ENDOCRINOL METAB, 1987 Dec; 65(6): 1118-1126.
<i>SPD</i>	Nankin, et al., <i>Decreased Bioavailable Testosterone in Aging Normal and Impotent Men</i> , J CLIN ENDOCRINOL METAB, 1986 Dec; 63(6):1418-11420.

SPD 19/14/03



RECEIVED

JUL 18 2003

SHEET 19 of 34
TECH CENTER 1600/2900

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617
(37 CFR 1.98 (b))			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SPD	Schaison, et al., <i>On the Role of Dihydrotestosterone in Regulating Luteinizing Hormone Secretion in Man</i> , J CLIN ENDOCRINOL METAB, 1980 Nov; 51(5): 1133-1137.
	Mitchell, et al., <i>Age Related Changes in the Pituitary-Testicular Axis in Normal Men; Lower Serum Testosterone Results from Decreased Bioactive LH Drive</i> , CLIN ENDOCRINOL (OXF), 1995 May; 42(5): 501-507.
	Korenman, et al., <i>Androgen Therapy of Hypogonadal Men with Transscrotal Testosterone Systems</i> , AM J MED, 1987 Sept; 83(3): 471-478.
	Zeginiadou, et al., <i>NonLinear Binding of Sex Steroids to Albumin and Sex Hormone Binding Globulin</i> , EUR J DRUG METAB PHARMACOKINET, 1997 Jul; 22(3): 229-235.
	Mendel, <i>Rates of Dissociation of Sex Steroid Hormones from Human Sex Hormone-Binding Globulin: a Reassessment</i> , J STEROID BIOCHEM MOL BIOL, 1990 Oct; 37(2): 251-255.
	Iqbal, et al., <i>Binding of Testosterone and Oestradiol to Sex Hormone Binding Globulin, Human Serum Albumin and Other Plasma Proteins: Evidence for Non-Specific Binding of Oestradiol to Sex Hormone Binding Globulin</i> , CLIN SCI, 1983 Mar; 64(3): 307-314.
	Mean, et al., <i>Study on the Binding of Dihydrotestosterone, Testosterone and Oestradiol Sex Hormone Binding Globulin</i> , CLIN CHIM ACTA, 1977 Oct 1; 80(1): 171-180.
	Belgorosky, et al., <i>Changes in Serum Sex Hormone-Binding Globulin and in Serum Non-Sex Hormone-Binding Globulin-Bound Testosterone During Prepuberty in Boys</i> , J STEROID BIOCHEM, 1987; 27(1-3): 291-295.
	Shanbhag, et al., <i>The Temperature Dependence of the Binding of 5 Alpha-Dihydrotestosterone and Estradiol to the Sex Hormone Globulin (SHBG) of Human Plasma</i> , J STEROID BIOCHEM, 1986 Feb; 24(2): 549-555.
	Nakhla, et al., <i>Stimulation of Prostate Cancer Growth by Androgens and Estrogens Through the Intermediacy of Sex Hormone-Binding Globulin</i> , ENDOCRINOLOGY 1996 Oct; 137(10): 4126-4129.
	Meikle, et al., <i>Familial Effects on Plasma Sex-Steroid Content in Man: Testosterone, Estradiol and Sex-Hormone-Binding Globulin</i> , METABOLISM, 1982 Jan; 31(1): 6-9.
SPD	Bartsch, <i>Interrelationships Between Sex Hormone-Binding Globulin and Testosterone, 5 alpha-dihydrotestosterone and Oestradiol-17 beta in Blood of Normal Men</i> , MATURITAS, 1980 Jul; 2(2): 109-118.

SPD 10/14/03



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

590	Signorello, et al., <i>Serum Steroids in Relation to Prostate Cancer Risk in a Case-Control Study (Greece)</i> , CANCER CAUSES CONTROL, 1997 Jul; 8(4): 632-636.
	Gann, et al., <i>Prospective Study of Sex Hormone Levels and Risk of Prostate Cancer</i> , J NATL CANCER INST, 1996 Aug 21; 88(16): 1118-1126.
	Plymate, et al., <i>Effects of Sex Hormone Binding Globulin (SHBG) on Human Prostatic Carcinoma</i> , J STEROID BIOCHEM MOL BIOL, 1991; 40(4-6): 833-839.
	Bartsch, et al., <i>Interrelationships Between Sex Hormone-Binding Globulin and 17 beta-Estradiol, Testosterone, 5 alpha-Dihydrotestosterone, Thyroxine, and Triiodothyronine in Prepubertal and Pubertal Girls</i> , J CLIN ENDOCRINOL METAB, 1980 Jun; 50(6): 1053-1056
	Schottner, et al., <i>Lignans Interereng with 5 alph-Dihydrotestosterone Binding to Human Sex Hormone-Binding Globulin</i> , J NAT PROD, 1988 Jan; 61(1): 119-121.
	Bocchinfuso, et al., <i>Expression and Differential Glycosylation of Human Sex Hormone-Binding Globulin by Mammalian Cell Lines</i> , MOL ENDOCRINOL, 1991 Nov; 5(11): 1723-1729.
	Tsai, et al., <i>Metabolic Approaches to Enhance Transdermal Drug Delivery. 1. Effect of Lipid Synthesis Inhibitors</i> , J PHARM SCI, 1996 Jun; 85(6): 643-648.
	Man, et al., <i>Optimization of Physiological Lipid Mixtures for Barrier Repair</i> , J INVEST DERMATOL, 1996 May; 106(5): 1096-1101.
590	Labrie, et al., <i>Physiological Changes in Dehydroepiandrosterone are not Reflected by Serum Levels of Active Androgens and Estrogens but of their Metabolites: Intracrinology</i> , J CLIN ENDOCRINOL METAB, 1997 Aug; 82(8): 2403-2409.
	The Testosterone Source, http://www.testosteronesource.com
590	Bonney, <i>Hormone Replacement Therapy for Men</i> , AMERICAN CLINICAL LABORATORY, November/December 1997, http://iscpubs.com/pubs/acl/acl1197.html
	Miller, <i>Benign Prostatic Hyperplasia: Nutritional and Botanical Therapeutic Options</i> , http://www.thorne.com/altmedrev/b-p-h.html
	Los Gatos Longevity Institute, <i>Andropausal</i> , http://www.antiaging.com/andropause.html
590	Grinspoon, et al, <i>Body Composition and Endocrine Function in Women with Acquired Immunodeficiency Syndrome Wasting</i> , J. CLIN ENDOCRINOL METAB, 1997 May; 82(5): 1332-7.

590 10/14/02



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

590	Navarro, et al., <i>Salivary Testosterone in Postmenopausal Women with Rheumatoid Arthritis</i> , J RHEUMATOL, 1998 Jun; 25(6): 1059-62.
	Bloch, et al. <i>Pituitary-Adrenal Hormones and Testosterone Across the Menstrual Cycle in Women with Premenstrual Syndrome and Controls</i> , BIOL PSYCHIATRY, 1998 Jun 15; 43(12): 897-903.
	Khosla, et al., <i>Relationship of Serum Sex Steroid Levels and Bone Turnover with Bone Mineral density in Men and Women: a Key Role for Bioavailable Estrogen</i> , J CLIN ENDOCRINOL METAB, 1998 Jul; 83(7): 2266-74.
	Padova, et al., <i>Pubarche Induction with Testosterone Treatment in Women with Panhypopituitarism</i> , FERTIL STERIL, 1996 Feb; 65(2): 437-9.
	Tutten, et al., <i>Discrepancies Between Genital Responses and Subjective Sexual Function during Testosterone Substitution in Women with Hypothalamic Amenorrhea</i> , PSYCHOSOM MED, 1996 May-Jun; 58(3): 234-41.
	Casson, et al., <i>Androgen Replacement Therapy in Women: Myths and Realities</i> , INT J FERTIL MENOPAUSAL STUD; 1996 Jul-Aug; 41(4):412-22.
	Davis, et al., <i>Clinical Review 82: Androgens and the Postmenopausal Woman</i> , J. CLIN ENDOCRINOL METAB, 1996 Aug; 81(8): 2759-63.
	Booji, et al., <i>Androgens as Adjuvant Treatment in Postmenopausal Female Patients with Rheumatoid Arthritis</i> , ANN RHEUM DIS, 1996 Nov; 55(11): 811-5.
	Bancroft, et al., <i>Androgens and the Menopause; a Study of 40-60-Year-Old Women</i> , CLIN ENDOCRINOL (OXF), 1996 Nov; 45(5): 577-87.
	Davis, et al., <i>Use of Androgens in Postmenopausal Women</i> , CURR OPIN OBSTET GYNECOL, 1997 Jun; 9(3): 177-80.
	Rouru, et al., <i>Serum Leptin Concentrations in Women with Polycystic Ovary Syndrome</i> , J CLIN ENDOCRINOL METAB, 1997 Jun; 82(6): 1697-700.
	Mantzoros, et al., <i>Leptin Concentrations in the Polycystic Ovary Syndrome</i> , J CLIN ENDOCRINOL METAB, 1997 Jun; 82(6): 1687-91.
	Krahe, et al., <i>Risk Factors for Decreased Bone Density in Premenopausal Women</i> , BRAZ J MED BIOL RES, 1997 Sep; 30(9): 1061-6.
	Greendale, et al., <i>Endogenous Sex Steroids and Bone Mineral Density in Older Women and Men: the Rancho Bernardo Study</i> , J BONE MINER RES, 1997 Nov; 12(11): 1833-43.
590	Goggin, et al., <i>The Relationship of Mood, Endocrine, and Sexual Disorders in Human Immunodeficiency Virus Positive (HIV+) Women: an Exploratory Study</i> , PSYCHOSOM MED, 1998 Jan-Feb; 60(1): 11-6.

298 12/14/03

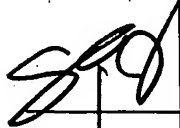




Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

	Zamberlan, et al., <i>Effect of Hyperandrogenism and Menstrual Cycle Abnormalities Bone Mass and Bone Turnover in Young Women</i> , CLIN ENDOCRINOL (OXF), 1998 Feb; 48(2): 169-73.
	Sinha-Hikim, et al., <i>The Use of a Sensitive Equilibrium Dialysis Method for the Measurement of Free Testosterone Levels in Healthy, Cycling Women and in Human Immunodeficiency Virus-Infected Women</i> ; J CLIN ENDOCRINOL METAB, 1998 Apr; 83(4): 1312-8.
	Heikkila, et al., <i>Serum Androgen-Anabolic Hormones and the Risk of Rheumatoid Arthritis</i> , ANN RHEUM DIS, 1998 May; 57(5): 281-5.
	Watts, et al. <i>Comparison of Oral Estrogens and Estrogens Plus Androgen on Mineral Density, Menopausal Symptoms, and Lipid-Lipoprotein Profiles in Surgical Menopause</i> , OBSTET GYNECOL, 1995 Apr; 85(4):529-37.
	Heiss, et al., <i>Associations of Body Fat Distribution, Circulating Sex Hormones Bone Density in Postmenopausal Women</i> , J CLIN ENDOCRINOL METAB, 1995 May; 80(5): 1591-6.
	Pedersen, et al., <i>Relationship Between Sex Hormones, Body Composition and Metabolic Risk Parameters in Premenopausal Women</i> , EUR J ENDOCRINOL, 1995 Aug; 133(2): 200-6.
	Van Gaal, et al., <i>Sex Hormones, Body Fat Distribution, Resting Metabolic Rate and Glucose-Induced Thermogenesis in Premenopausal Obese Women</i> , INT J OBES RELAT METAB DISORD, 1994 May; 18(5): 333-.
	Sands, et al., <i>Exogenous Androgens in Postmenopausal Women</i> , AM J MED, 1995 Jan 16; 98(1A): 76S-79S.
	Bernini, et al., <i>Endogenous Androgens and Carotid Intimal-Medial Thickness in Women</i> , J CLIN ENDOCRINOL METAB, 1999 Jun; 84(6): 2008-12.
	van Honk, et al., <i>Correlations Among Salivary Testosterone, Mood, and Selective Attention to Threat in Humans</i> , HORM BEHAV, 1999 Aug; 36(1): 17-24.
	Good, et al., <i>Bone Mineral Density and Body Composition in Lean Women with Polycystic Ovary Syndrome</i> , FERTIL STERIL, 1999 Jul; 72(1): 21-5.
	Buckler, et al., <i>Which Androgen Replacement Therapy for Women?</i> , J CLIN ENDOCRINOL METAB, 1998 Nov; 83(11):3920-4.
	Cutolo, et al., <i>Hypothalamic-Pituitary-Adrenocortical Axis Function in Premenopausal Women with Rheumatoid Arthritis Not Treated with Glucocorticoids</i> , J RHEUMATOL, 1999 Feb; 26(2): 282-8.
	Baumgartner, et al., <i>Predictors of Skeletal Muscle Mass in Elderly Men and Women</i> , MECH AGEING DEV, 1999 Mar 1; 107(2): 123-36.

 10/14/03



RECEIVED

JUL 18 2003

SHEET 23 of 34
TECH CENTER 1600/2900

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILED DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SAO	Exton, et al., Cardiovascular and Endocrine Alterations after Masturbation-Induced Orgasm in Women, PSYCHOSOM MED, 1999 May-Jun; 61(3): 280-9.
SAO	Davis, Androgen Replacement in Women: a Commentary, J CLIN ENDOCRINOL METAB, 1999 Jun; 84(6): 1886-91.
SAO	Rako, Testosterone Deficiency: a Key Factor in the Increased Cardiovascular Risk to Women Following Hysterectomy or with Natural Aging? J WOMENS HEALTH, 1998 Sep; 7(7): 825-9.
SAO	ABCNEWS.com: Testosterone Patch Increases Women's Sex Drive, http://abcnews.go.com/sections/living/DailyNews/testosterone990615.html.
SAO	Miller, et al., Transdermal Testosterone Administration in Women with Acquired Immunodeficiency Syndrome Wasting: a Pilot Study, J CLIN ENDOCRINOL METAB, 1998 Aug; 83(8): 2717-25.
SAO	Graeme's Testosterone Page, http://www.voyager.co.nz/~gtuck/graeme/.
SAO	Belgorosky, Sex Hormone Binding Globulin Response to Testosterone. An Androgen Sensitivity Test, ACTA ENDOCRINOL (COPENH), 1985 May; 109(1): 130-138.
SAO	Testosterone, Chapters 1-16 (1999).
SAO	Choi, et al., Transdermal Dihydrotestosterone Therapy and its Effects on Patients with Microphallus, J UROL, 1993 Aug; 150(2 Pt 2): 657-660.
	Ernesti, et al., Absorption and Metabolism of Topically Applied Testosterone in an Organotypic Skin Culture, SKIN PHARMACOL, 1992; 5(3): 146-153.
	Findlay, et al., Treatment of Primary Hypogonadism in Men by the Transdermal Administration of Testosterone, J CLIN ENDOCRINOL METAB, 1989 Feb; 68(2): 369-373.
	Kao, et al., Skin Absorption and Cutaneous First Pass Metabolism of Topical Steroids: in vitro Studies with Mouse Skin in Organ Culture, J PHARMACOL EXP THER, 1987 May; 241(2): 482-487.
SAO	Wang, et al., PHARMACOKINETICS OF TRANSDERMAL TESTOSTERONE GEL IN HYPOGONADAL MEN, ENDO '98 SUBMISSION PROGRAM, 1998N ABSTRACT FORM.
SAO	AndroGel, Information Release, date unknown.

EXAMINER

DATE CONSIDERED

10/14/03

EXAMINER: Initial citation consider d. Draw line through citation if n t i n c n f r m a n c e a n d n o t c o n s i d e r d. I n c l u d e c o p y o f t h i s f o r m w i t h n e x t c o m m u n i c a t i o n t o a p p l i c a n t.



RECEIVED

JUL 18 2003

SHEET 24 of 34
TECH CENTER 1600/2900

Form PTO - 1449 (Modified)

FORM PTO-1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.
01917581SERIAL NO.
10/046,454APPLICANT
R. DudleyFILING DATE
October 19, 2001GROUP
1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		Manos, <i>FDA Approves Gel to Treat Low Testosterone Levels</i> , www.testocrema.com (Downloaded 5/09/01).
590		Unimed Pharmaceuticals' Androgel Shows Solid Promise for Men, Fertility Industry News, www.INCIID.com (August 19, 1998).
		Lacayo, <i>Are You Man Enough?</i> , Time Europe, www.Time.com , Vol. 155, No. 16 (April 24, 2000).
		MacroChem Accelerates Development of Top For Impotence, www.pslgroup.com (April 10, 1997).
590		Kaufman, <i>Efficacy and Safety of a New, Topical Testosterone Gel (T-gel) For Male Hormonal Supplementation</i> , International Journal of Impotence Research, Vol. 12, Supplement 3, p. S75 (B9) (September 2000).
		Longstreth, et al., <i>Transdermal Testosterone Pharmacokinetics Remain Unchanged With Prolonged Treatment</i> , Unimed Pharmaceuticals (October 31, 2000).
		Ringham, et al., <i>Dose Proportionality and Systemic Bioavailability of a Testosterone Topical Gel In Hypogonadal Men</i> , Unimed Pharmaceuticals (October 31, 2000).
		Miller, et al., <i>Androgen Deficiency in Women with Hypopituitarism</i> , The Journal of Clinical Endocrinology & Metabolism, Vol. 86, No.2, pp. 561-567 (2001).
		Veldhuis, et al., <i>Muting of Androgen Negative Feedback Unveils Impoverished Gonadotropin-Releasing Hormone/Luteinizing Hormone Secretory Reactivity in Healthy Older Men</i> , The Journal of Clinical Endocrinology & Metabolism, Vol. 86, No. 2, pp. 529-535. (2001)
590		Women and HIV, Women and HIV Discussion Paper, pp. 1-12 (1/98).
EXAMINER	590	DATE CONSIDERED 10/14/03
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.		



Form PTO - 1449 (Modified)

FORM PTO-1449
(Modified)U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICEINFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.
01917581SERIAL NO.
10/046,454APPLICANT
R. DudleyFILING DATE
October 19, 2001GROUP
1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

<i>SAD</i>	Swerdloff, et al., <i>Long Term Pharmacokinetics of Transdermal Testosterone Gel Versus Testosterone Patch in Hypogonadal Men</i> , 2347 Male Reproductive Poster Session, Board 578 (June 22, 2000).
	Wang, et al., <i>Effects of Transdermal Testosterone Gel on Bone Turnover Markers and Bone Mineral Density in Hypogonadal Men</i> , 2348 Male Reproductive Poster Session, Board 579 (June 22, 2000).
	Wang, et al., <i>Effects of Transdermal Testosterone Gel on Bone Turnover Markers and Bone Mineral Density in Hypogonadal Men</i> , <i>Clinical Endocrinology</i> , Vol. 54, pp. 1-13 (2001).
	Wang, et al., <i>Transdermal Testosterone Gel Improves Sexual Function, Mood, Muscle Strength, and Body Composition Parameters in Hypogonadal Men</i> , <i>Basic Science: Reproduction-Gonadal Control (Male)</i> , Male Reproduction Oral Session, No. 1360 (June 24, 2000).
	<i>Unimed Pharmaceuticals' Androgel Shows Solid Promise for Men</i> ; Fertility Industry News, www.INCIID.com (August 19, 1998).
	<i>Bentley Pharmaceuticals Announces License Agreement for Its Topical Testosterone Gel Formulation</i> ; Li, www.UVentures.com (December 18, 2000).
<i>SAD</i>	Ruggs, <i>Unimed Begins Pivotal Clinical Trial For Innovative Testosterone Gel</i> , Unimed News Release, pp. 1-2 (March 31, 1997).
	Androgel 1% (testosterone-gel) CIII; www.Androgel.com, pp. 1-2.
<i>SAD</i>	Wang, et al., <i>Effects of Transdermal Testosterone Gel on Bone Turnover Markers and Bone Mineral Density in Hypogonadal Men</i> , <i>Clinical Science: Reproduction (Male)-Prostate</i> , Male Reproduction Poster Session, No. 2348 (June 22, 2000).
<i>SAD</i>	Swerdloff, et al., <i>Long Term Pharmacokinetics of Transdermal Testosterone Gel Versus Testosterone Patch in Hypogonadal Men</i> , <i>Clinical Science: Reproduction (Male)-Prostate</i> , Male Reproduction Poster Session, No. 2347 (June 22, 2000).
	<i>Trials for the Treatment of Wasting, AIDS-Treatment-Data-Network</i>, www.aidsinfonyc.org (Downloaded 10/8/98).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	TAB	PATENT NUMBER	ISSUE DATE	PATENTEE	CLASS	SUB CLASS	FILING DATE
SDF		6 0 3 7 3 4 6	03/14/00	Doherty, Jr., et al.			
		6 0 7 5 0 2 8	06/13/00	Graham			
SDF		6 0 7 7 8 4 1	06/20/00	Sui, et al.			
		6 0 8 7 3 6 8	07/11/00	Macor, et al.			
		6 1 2 7 3 6 3	10/03/00	Doherty, et al.			
		6 1 5 6 7 5 3	12/05/00	Doherty, et al.			

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SDF		De Lunardo, et al., <i>Determination of Acceptability of 2 Cutaneous Estradiol Gels, In A Dose of 1.5 mg Daily</i> , J. Gynecol. Obstet. Biol. Reprod. (Paris), Vol. 29, No. pp. 509-516, (September 2000)
		Zartarian, et al., <i>Comparative Evaluation of the Acceptability of a New Estradiol Gel TX11323(A) and a Reference Gel</i> , J. Gynecol. Obstet. Biol. Reprod. (Paris), Vo. 25, No. 5, pp. 451-456 (1996).
		Simon, et al., <i>The Absorption of Oral Micronized Progesterone: The Effect of Food, Dose Proportionality, and Comparison With Intramuscular Progesterone, Fertility and Sterility</i> , Vol. 60, No. 1, pp. 26-33 (July 1993).
		Vaubourdolle, et al., <i>Effect of Dihydrotestosterone on the Rate of Ethanol Elimination in Healthy Men</i> , Alcohol Clin. Exp. Res., Vol. 15, No. 2, pp. 238-240 (March 1991).
		Fournier, et al., <i>Value of a Percutaneous Estrogen Solution in Stopping Lactation</i> , Rev. Fr. Gynecol. Obstet., Vol. 85, No. 12, pp. 715-719 (December 1990).
		Simon, et al., <i>Percutaneous Absorption of 17 Beta-Estradiol in Ovariectomized Rhesus Monkeys: Skin and Serum Pharmacokinetics, Fertility and Sterility</i> , Vol. 53, No. 3, pp. 561-565 (March 1990).
		Rodriguez, <i>Study of Drug to Preserve Lean Muscle Mass Recruiting Patients</i> , APLA 9701: Study Recruiting Patients, www.apla.org (Downloaded 10/8/98).
		HIV Wasting Treatment: Nandrolone Decanoate, www.hivinsite.ucsf.edu (August 1, 1995).
SDF		Vergel, <i>Anabolic Steroids: A Practical Guide</i> , CRIA Update, Vol. 7, No. 3 (Summer 1998).
EXAMINER	DATE CONSIDERED 10/14/03	
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not consider d. Include c py of this form with n xt communication to applicant.		



RECEIVED

JUL 18 2003

SHEET 27 of 34

TECH CENTER 1600/2900

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SAF	HIV Wasting Syndrome, www.thebody.com (May 1997).
SAF	Tirassa, et al., High-Dose Anabolic Androgenic Steroids Modulate Concentrations of Nerve Growth Factor and Expression of its Low Affinity Receptor (p75-NGFr) in Male Rat Brain, Journal of Neuroscience Research, Vol. 47, No. 2, pp. 198-207 (January 15, 1997).
	Mooney, Frequency of Administration - Testosterone & Nandrolone, Vol. 1, No. 4, www.medibolics.com (Downloaded 10/8/98).
SAF	Anabolic Steroids, Project Inform, Anabolic Steroids Quick Sheet (December 1997).
SAF	Anabolic Steroid Boosts Weight, GMHC Treatment Issues, Vol. 10, No. 9 (September 1996).
	Anabolic Steroids, Project Inform Hotline Handout, www.projinf.org. (Downloaded 10/8/98).
	Anabolic Steroids - A Simple Facts Sheet From The Network, www.network/simple/steroids. (Downloaded 10/27/98).
	USP Drug Information - Anabolic Steroids (Systemic), Mayo Clinic, www.mayohealth.org (Downloaded 10/8/98).
SAF	Mooney, Anabolic Steroids For AIDS Therapy: Differences Between Analogs, No. 1, www.digiweb.com. (July 1998).
	Bisschop, et al., Effects of Nandrolone Decanoate on Respiratory and Peripheral Muscles in Male and Female Rats, www.uth.tms.edu. (1996, Downloaded 10/8/98).
	HIV/AIDS Clinical Trials in the New Orleans Area, ACTG 329, www.tmc.tulane.edu (Downloaded 10/8/98).
	Need, et al., Effects of Nandrolone Therapy on Forearm Bone, www.medmedia.com (Downloaded 10/8/98).
	Testocrema - No Shots, No Pills, No Patches, www.testocrema.com (Downloaded 7/10/00).
SAF	Testosterone Therapy - for Women?, Health News, www.onhealth.com (May 7, 1996).
SAF	ENDO 99: Testosterone Patch Effective For Diminished Sexual Function in Surgically Menopausal Women, www.pslgroup.com (June 15, 1999).
	Howland, The "Other" Hormone Replacement Therapy: Testosterone in Menopausal Women, HealthGate, www.bewell.com (8/7/00).
	Menopause and Testosterone, www.womenshealth.com (Downloaded 8/7/00).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

10/14/03



RECEIVED
JUL 18 2003
TECH CENTER 1600/2900
SHEET 12800/2900

Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

		<i>Data Supports Safety of Estratest For Men, Doctor's Guide, www.pslgroup.com (March 9, 1998).</i>
<i>SAD</i>		<i>Testosterone's Role in the Female Sex Drive, USA Today News, www.usatoday.com (April 8, 1996).</i>
<i>SAD</i>		<i>Bartnof, Testosterone Therapy Causes Menstruation to Return in Women with AIDS-Related Wasting, www.hivandhepatitis.com (10/12/99).</i>
<i>SAD</i>		<i>Testosterone 'Aids Post-Menopausal Women', BBC News Online: Health, www.bbc.co.uk. (June 14, 1999).</i>
		<i>Alternative to Viagra For Women!, www.mdhealthline.com (Downloaded 8/7/00).</i>
		<i>Kalantaridou, et al., Transdermal Testosterone Replacement for Young Women with Spontaneous Premature Ovarian Failure: A Pilot Study, No. 2322, www.abstracts-on-1 (Downloaded 8/7/00).</i>
<i>SAD</i>		<i>Rosano, et al., Antianginal and Lipid Lowering Effect of Chronic Oral Androgen Supplementation in Elderly Male Patients with Coronary Heart Disease, JACC, Abstract No. 835-4 (February 2001)</i>
		<i>Mollgaard, et al., Permeation of Estradiol Through the Skin - Effect of Vehicles, International Journal of Pharmaceutics, Vol. 15, pp. 185-197 (1983).</i>
		<i>Ostrega, et al., Significance of Vehicle Composition II: Prediction of Optimal Vehicle Composition, Journal of Pharmaceutical Sciences, Vol. 60, No. 8, pp. 1180-1183 (August 1971).</i>
		<i>Cooper, et al., Effect of Fatty Acids and Alcohols on the Penetration of Acyclovir Across Human Skin in Vitro, Journal of Pharmaceutical Sciences, Vol. 74, No. 6, pp. 688-689 (June 1985).</i>
		<i>Ostrega, et al., Significance of Vehicle Composition I: Relationship Between Topical Vehicle Composition, Skin Penetrability, and Clinical Efficacy, Journal of Pharmaceutical Sciences, Vol. 60, No. 8, pp. 1175-1179 (August 1971).</i>
		<i>Maibach, et al., The Effect of DMSO on Percutaneous Penetration of Hydrocortisone and Testosterone in Man, Annals New York Academy of Sciences, pp. 423-427.</i>
		<i>Mollgaard, et al., Vehicle Effect on Topical Drug Delivery, Acta Pharm. Suec., Vol. 20, pp. 433-442 (1983).</i>
<i>SAD</i>		<i>Misra, et al., Biphasic Testosterone Delivery Profile Observed With Two Different Transdermal Formulations, Pharmaceutical Research, Vol. 14, No. 9, pp. 1264-1268 (1997).</i>
EXAMINER		DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not consider d. Include copy of this form with next communication to applicant.		



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER DOCUMENTS (Including Author, Title, Date, Place of Publication)

SPD	Sitruk-Ware, <i>Percutaneous and Transdermal Oestrogen Replacement Therapy</i> , <i>Annals of Medicine</i> , Vol. 25, pp. 77-82 (1993).
	Goodman, et al., <i>Action of Skin Permeation Enhancers Azone, Oleic Acid and Decylmethyl Sulphoxide: Permeation and DSC Studies</i> .
	Woodford, et al., <i>Optimization of Bioavailability of Topical Steroids: Thermodynamic Control</i> , <i>The Journal of Investigative Dermatology</i> , Vol. 79, No. 6, pp. 388-391 (December 1982).
	<i>Androgel</i> , <i>The Medical Letter On Drugs And Therapeutics</i> , Vol. 42 (Issue 1080), pp. 49-52 (June 12, 2000).
	<i>Never Too Buff</i> , <i>Time Europe</i> , www.time.com, Vol. 155, No. 16 (April 24, 2000).
	<i>Androgel Package Insert</i> , Dec. 2000
SPD	Jarkander-Rolff, et al., <i>Transdermal Application of A Testosterone Gel - A Pharmacokinetic Study</i> .
	<i>Androgel - Phase-III Clinical Trial</i>, <i>Gynecology</i> (Undated).
	Gefael, <i>Graeme's Testosterone Page</i>, www.voyager.co.nz (5/12/00).
	<i>Estrogel</i>, www.netdoktor.dk/medicin/Fakta/Estrogel (Downloaded 6/26/01).
	<i>La Sexualite . . . L'Androgel, Le Gel Miracle</i>, www.aci-multimedia.net/feminin/androgel (Downloaded 5/9/01).
	Stehli, et al., <i>Info . . . Info . . . Info . . . - Androgel</i>, www.mageos.france.com/nade38/androgel (Downloaded 5/9/01).
SPD	Cherrier, et al., <i>T-Gel Study: Cognitive Effects of Exogenous Testosterone Manipulation in Hypogonadal Men</i> (6/7/99).
	Bentley Pharmaceuticals Announces Research and Licensing Agreements For Intranasal Pain Management and Topical Hormone Replacement Therapy, www.bentleypharm.com (downloaded 11/17/01).
SPD	Gennaro, <i>Remington: The Science and Practice of Pharmacy</i> , 20 th Edition, Chapter 44, pp. 842-843 (2000).
SPD	Walters, <i>Penetration Enhancers and Their Use in Transdermal Therapeutic Systems</i> , pp. 202-227 (1990).
EXAMINER	DATE CONSIDERED
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.	

10/14/03

Form PTO – 1449 (Modified)

FORM PTO-1449 (Modified) (37 CFR 1.98 (b))	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
		APPLICANT R. Dudley	
		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

U.S. PATENT DOCUMENTS					
Examiner Initials	Date No. 1	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code ² (if known)			
5/8		US-3888995	06/10/1975	Katz, et al.	
		US-4442094	04/10/1984	Atkinson, et al.	
		US-4496556	01/29/1985	Orentreich	
		US-4563473	01/07/1986	Hofman, et al.	
		US-4695465	09/22/1987	Kigasawa, et al.	
		US-4863970	09/05/1989	Patel, et al.	
		US-5053227	10/01/1991	Chiang, et al.	
		US-5059603	10/22/1991	Rubin	
		US-5152997	10/06/1992	Ebert, et al.	
		US-5324521	06/28/1994	Gertner, et al.	
		US-5332577	07/26/1994	Gertner, et al.	
		US-5413794	05/09/1995	Suzuki, et al.	
		US-5744162	04/28/1998	Okabe, et al.	
		US-5760096	06/02/1998	Thornfeldt, et al.	
		US-5874074	02/23/1999	Smith	
		US-5932227	08/03/1999	Higo, et al.	
		US-5955455	09/21/1999	Labrie	
	5/8		US-6010716	01/04/2000	Saunal, et al.
		US-6117446	09/12/2000	Place	
		US-6238284	05/29/2001	Dittgen, et al.	

[illegible]

Examiner Signature		Date Considered	10/14/03
-----------------------	---	--------------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.**



Form PTO - 1449 (Modified)

FORM PTO-1449 (Modified)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	ATTY. DOCKET NO. 01917581	SERIAL NO. 10/046,454
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		APPLICANT R. Dudley	
(Use several sheets if necessary)		FILING DATE October 19, 2001	GROUP 1617

(37 CFR 1.98 (b))

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
SD		D. OSBORNE, ET AL., "Skin Penetration Enhancers Cited in the Technical Literature," Pharmaceutical Technology, p. pp. 58, 60, 62, 64 & 66 (November 1997).	
		International Search Report - Application No. PCT/US 01/27205, Reference No. 01736544 (International Filing Date: 08/29/2001).	
		International Search Report - Application No. PCT/US 01/27202, Reference No. 01736571 (International Filing Date: 08/29/2001).	
SD		International Search Report - Application No. PCT/US 01/27199, Reference No. 01902267 (International Filing Date: 08/29/2001).	

Examiner Signature		Date Considered	10/14/03
-----------------------	--	--------------------	----------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.